



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : ZHI et al.  
Serial No. : 10/590,119  
Filed : August 18, 2006

Art Unit : 1751  
Examiner : Unknown  
Conf. No. : 1033  
Cust. No. : 20985

Title : ANDROGEN RECEPTOR MODULATOR COMPOUNDS AND METHODS

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

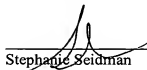
Dear Sir:

Transmitted herewith are an Information Disclosure Statement (3 pages), Forms PTO-1449 (5 pages), cited non U.S. patent references and a return postcard for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a first office action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:



The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

  
Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 18202-028US1 / 1112US  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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**INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE  
WITH 37 C.F.R. §§ 1.97-1.98**

Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (5 pages) and copies of the cited non U.S. Patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of items noted below. Items BT, BX, and CI (Patent Nos. WO 01/27086, WO 02/22585, and WO 98/22432, respectively) are in the Japanese language. Items BT and BX are supplied with English language equivalents, items BN (US 6845378) and BM (US 6777427), respectively. Item CI is supplied with an English language abstract, item CO (Derwent abstract). Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following pending U.S., International and National Phase Applications that have one or more common inventors and/or are commonly owned:

<b><u>Docket No.</u></b>	<b><u>U.S.S.N.</u></b>	<b><u>Filed</u></b>	<b><u>Publ. No.</u></b>
002007/1002F	08/141,246	10/22/93	n/a
002009/1002H	08/141,496	10/22/93	n/a
002017/1002P	11/300,039	12/13/05	2006-0106072
004003/1026C	10/847,732	05/17/04	2004-0209839
005003/1028C	10/360,580	02/05/03	2004-0019072
013002/1062B	10/238,363	09/09/02	2003-0186970
013003/1062C	11/340,282	01/25/06	n/a
015003/1073C	11/165,769	06/23/05	2005-0288350
017002/1081B	11/344,690	01/31/06	2006-0128740
018001/1082	10/080,503	02/22/02	2002-0183314
018002/1082B	11/601,251	11/17/06	n/a
020002/1088B	11/411,676	04/25/06	2006-0194827
022US1/1096US	10/564,578	01/13/06	n/a
027US1/1110US	10/589,920	08/17/06	n/a
030US1/1111US	10/566,569	01/31/06	n/a
048001/1087	10/684,212	10/11/03	2004-0152717
057002/1091B	11/445,844	06/02/06	2006-0223839
072P01/P1123	60/753,302	12/21/05	n/a

<b><u>Docket No.</u></b>	<b><u>Intl. No.</u></b>	<b><u>Filed</u></b>	<b><u>Publ. No.</u></b>
023WO1/1097PC	PCT/US04/023788	07/16/04	2005/009104
024WO1/1098PC	PCT/US04/023093	07/16/04	2005/016255
026WO1/1100PC	PCT/US04/023010	07/16/04	2005/010202
028WO1/1112PC	PCT/US05/07867	03/11/05	2005/090282
068WO1/1119PC	PCT/US06/23111	6/12/06	Awaiting
069WO1/1124PC	PCT/US06/26067	06/30/06	Awaiting

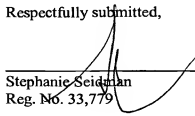
Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant : ZHI et al.  
Serial No. : 10/590,119  
Filed : August 18, 2006

Attorney's Docket No.: 18202-028US1 / 1112US  
**Information Disclosure Statement**

Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application.

Respectfully submitted,



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Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 18202-028US1 / 1112US  
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Sheet 1 of 5

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 18202-028US1/1112US	Application No. 10/590,119
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)		Applicant <b>ZHI et al.</b>	
		Filing Date August 18, 2006	Group Art Unit 1751

(37 CFR §1.98(b))

### U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
N.C./	AA	2002/0183314	12/05/02	Higuchi et al.	514	224.5	02/22/02
	AB	2002/0183346	12/05/02	Zhi et al.	514	291	02/22/02
	AC	2003/0055094	03/20/03	Sun et al.	514	379	07/31/02
	AD	3710795	01/16/73	Higuchi et al.	424	424	09/29/70
	AE	3847988	11/12/74	Gold	562	802	12/23/71
	AF	4044126	08/23/77	Cook et al.	514	180	07/09/76
	AG	4097578	06/27/78	Peronnet et al.	514	389	10/21/76
	AH	4202895	05/13/80	Inaba et al.	514	266.31	06/14/74
	AI	4328245	05/04/82	Yu et al.	514	530	02/13/81
	AJ	4358603	11/09/82	Yu	560	2	04/16/81
	AK	4364923	12/21/82	Cook et al.	424	46	04/30/81
	AL	4409239	10/11/83	Yu	514	530	01/21/82
	AM	4410545	10/18/83	Yu et al.	514	530	05/10/82
	AN	4414209	11/08/83	Cook et al.	514	180	06/13/77
	AO	4522811	06/11/85	Eppstein et al.	514	2	07/08/82
	AP	4636505	01/13/87	Tucker	514	256	07/15/83
	AQ	4981784	01/01/91	Evans et al.	435	6	11/30/88
	AR	5033252	07/23/91	Carter	53	425	07/30/90
	AS	5052558	10/01/91	Carter	206	439	07/27/90
	AT	5071773	12/10/91	Evans et al.	436	501	10/20/87
	AU	5323907	06/28/94	Kalvelage	206	531	03/15/93
	AV	5506102	04/09/96	McDonnell	435	6	10/28/93
	AW	5677336	10/14/97	Jones et al.	514	546	10/21/93
	AX	5688810	11/18/97	Jones et al.	514	311	06/05/95
	AY	5693646	12/02/97	Jones et al.	514	285	06/05/95
	AZ	5696130	12/09/97	Jones et al.	514	291	06/05/95
	BA	5696133	12/09/97	Jones et al.	514	314	06/05/95

Examiner Signature

/Nizal Chandrakumar/

Date Considered

09/25/2010

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Disclosure Form (PTO-1449)



Sheet 2 of 5

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 18202-028US1/1112US	Application No. 10/590,119
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)		Applicant ZHI et al.	
		Filing Date August 18, 2006	Group Art Unit 1751
(37 CFR §1.98(b))			

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
↓	N.C./ BB	6017924	01/25/00	Edwards et al.	514	292	08/12/99
	BC	6358947	03/19/02	Zhi et al.	514	229.5	04/19/00
	BD	6380207	04/30/02	Coghlan et al.	514	285	02/13/98
	BE	6462038	10/08/02	Higuchi et al.	514	224.5	08/25/00
	BF	6506766	01/14/03	Coghlan et al.	514	285	07/05/02
	BG	6534516	03/18/03	Edwards et al.	514	285	11/24/99
	BH	6566372	05/20/03	Zhi et al.	514	312	08/24/00
	BI	6569896	05/27/03	Dalton et al.	514	493	08/23/01
	BJ	6667313	12/23/03	Hamann et al.	514	292	08/25/00
	BK	6673799	01/06/04	Taniguchi et al.	514	253.01	03/21/01
	BL	6696459	02/24/04	Jones et al.	514	285	10/14/97
	BM	6777427	03/21/02	Miyakawa et al.	514	311	09/14/01
	BN	6845378	04/19/01	Pauly et al.	707	101	06/12/01
	N.C./ BO	Re 28819	05/18/76	Thompson	514	174	04/16/75

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
↓	N.C./ BP	00/066590	11/09/00	PCT				
	BQ	01/016108	03/08/01	PCT				
	BR	01/016133	03/08/01	PCT				
	BS	01/016139	03/08/01	PCT				
	BT	01/27086	04/19/01	PCT				X+
	BU	02/066475	08/29/02	PCT				
	BV	02/068427	09/06/02	PCT				
	BW	02/16310	02/28/02	PCT				
	BX	02/22585	03/21/02	PCT				X+
	N.C./ BY	03/011824	02/13/03	PCT				

Examiner Signature Nizal Chandrakumar/	Date Considered 09/25/2010
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	


Sheet 3 of 5

Substitute Form PTO-949 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 18202-028US1/1112US	Application No. 10/590,119
<b>Information Disclosure Statement</b> <b>by Applicant</b> (Use several sheets if necessary)		Applicant ZHI et al.	
		Filing Date August 18, 2006	Group Art Unit 1751
(37 CFR §1.98(b))			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
/N.C./	BZ	03/037905	05/08/03	PCT				
	CA	04/016576	02/26/04	PCT				
	CB	05/000795	01/06/05	PCT				
	CC	0711768	05/15/76	EP				
	CD	1122242	08/08/01	EP				
	CE	800519	10/22/03	EP				
	CF	95/011215	04/27/95	PCT				
	CG	95/031722	11/23/95	PCT				
	CH	97/049709	12/31/97	PCT				
	CI	98/22432	05/28/98	PCT				X*
X* = An English language Derwent abstract is provided. X+ = An English language equivalent is provided.								

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
/N.C./	CJ	Abela Medici et al., "Cytotoxic compounds. Part 21. Chloro-, methoxy-, and methoxycarbonyl-derivatives of (bis-2-chloroethylamino)-phenols and -anilines," <i>Journal of the Chemical Society, Perkin Transactions 1, Organic and Bio-organic Chemistry</i> , 20:2258-2263, (1977).
	CK	Anlezark et al., "Bioactivation of dinitrobenzamide mustards by an E. coli B nitroreductase," <i>Biochemical Pharmacology</i> , 50:609-618, (1995).
	CL	Ansel, H.C., <i>Introduction to Pharmaceutical Dosage Forms</i> , Fourth Edition, Lea and Febiger, Philadelphia, P.A., p. 126, (1985).
	CM	Bains and Tacke, "Silicon chemistry as a novel source of chemical diversity in drug design," <i>Current Opinion in Drug Discovery and Development</i> , 6(4):526-543, (2003).
	CN	Berger et al., "Interaction of glucocorticoid analogues with the human glucocorticoid receptor," <i>Journal of Steroid Biochemistry and Molecular Biology</i> , 41:733-748, (1992).
	CO	Derwent English abstract for WO 98/22432, published May 28, 1998 entitled: "New N-acyl-aminoacid aniline derivatives-useful as anti-androgens for treating cancer, masculinisation, hirutism etc.," Accession Nbr. 8769118 [351].
	CP	Edwards et al., "Nonsteroidal androgen receptor agonists based on 4-(trifluoromethyl)-2H-pyran[3,2-g]quinolin-2-one," <i>Bioorganic Medicine and Chemistry Letters</i> , 9(7):1003-1008, (1999).
	CQ	Evans et al., "The steroid and thyroid hormone receptor superfamily," <i>Science</i> , 240:889-895, (1988).
	CR	Fingl et al., <i>The Pharmacological Basis of Therapeutics</i> , Ch. 1, Eds. Goodman and Gilman, Macmillan Publishing Co., New York, N.Y., pp. 1-46, (1975).

Examiner Signature Nizal Chandrakumar/	Date Considered 09/25/2010
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
Substitute Disclosure Form (PTO-1449)	



Sheet 4 of 5

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 18202-028US1/1112US	Application No. 10/590,119
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)		Applicant ZHI et al.	Group Art Unit 1751
		Filing Date August 18, 2006	
(37 CFR §1.98(b))			

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
/N.C./	CS	Gravatt et al., "DNA-directed alkylating agents. 6. Synthesis and antitumor activity of DNA minor groove-targeted aniline mustard analogues of pibenzimol (Hoechst 33258)," <i>Journal of Medicinal Chemistry</i> 37:4338-4345, (1994).
	CT	Hamann et al., "Synthesis and biological activity of a novel series of nonsteroidal, peripherally selective androgen receptor antagonists derived from 1,2-dihydropyridono[5,6-g]quinolines," <i>Journal of Medicinal Chemistry</i> , 41(4):623-639, (1998).
	CU	Higuchi et al., "4-Alkyl- and 3,4-dialkyl-1,2,3,4-tetrahydro-8-pyridono[5,6-g]quinolines potent, nonsteroidal androgen receptor agonists," <i>Bioorganic Medicine and Chemistry Letters</i> , 9(9):1335-1340, (1999).
	CV	Kong et al., "Effects of isosteric pyridone replacements in androgen receptor antagonists based on 1,2-dihydro- and 1,2,3,4-tetrahydro-2,2-dimethyl-6-trifluoromethyl-8-pyridono[5,6-g]quinolines," <i>Bioorganic Medicine and Chemistry Letters</i> , 10(5):411-414, (2000).
	CW	Michellys et al., "Design, synthesis, and structure-activity relationship studies of novel 6,7-locked-[7-(2-alkoxy-3,5-dialkylbenzene)-3-methylocta]-2,4,6-trienoic acids," <i>Journal of Medicinal Chemistry</i> , 46(19):4087-4103, (2003).
	CX	Niculescu-Duvaz et al., "Self-immolative nitrogen mustard prodrugs for suicide gene therapy," <i>Journal of Medicinal Chemistry</i> , 41:5297-5309, (1998).
	CY	Nogard, T., <i>Medicinal Chemistry A Biochemical Approach</i> , Oxford University Press, New York, N.Y., pp. 388-392, (1985).
	CZ	Palmer et al., "Hypoxia-selective antitumor agents. 3. Relationships between structure and cytotoxicity against cultured tumor cells for substituted N,N-bis(2-chloroethyl)anilines," <i>Journal of Medicinal Chemistry</i> , 33:112-121, (1990).
	DA	Palmer et al., "Hypoxia-selective antitumor agents. 5. Synthesis of water-soluble nitroaniline mustards with selective cytotoxicity for hypoxic mammalian cells," <i>Journal of Medicinal Chemistry</i> , 35:3214-3222, (1992).
	DB	Palmer et al., "Nitro analogues of chlorambucil as potential hypoxia-selective anti-tumour drugs," <i>Anti-Cancer Drug Design</i> , 5:337-349, (1990).
	DC	Panthanickal et al., "Structure-activity relationship of aniline mustards acting against B-16 melanoma in mice," <i>Journal of Medicinal Chemistry</i> , 22:1267-1269, (1979).
	DD	Pathirana et al., "Nonsteroidal human progesterone receptor modulators from the marine alga <i>Cymopolia barbatum</i> ," <i>Molecular Pharmacology</i> , 47:630-635, (1995).
	DE	Pooley et al., "Discovery and preliminary SAR studies of a novel, nonsteroidal progesterone receptor antagonist pharmacophore," <i>Journal of Medicinal Chemistry</i> , 41:3461, (1998).
	DF	Popp, "Synthesis of potential antineoplastic agents X. Preparation and reactions of aldehydes related to benzaldehyde mustard," <i>Journal of Medicinal Chemistry</i> , 7:210-212, (1964).
	DG	Prasmickiene et al., "Synthesis and study of the reactivity of p-bis(2-chloropropyl)amino]phenylalkanoic acids," <i>Izvestiya Akademii Nauk SSSR, Seriya Khimicheskaya</i> , 3:643-646, (1969).
	DH	Steinman et al., "1-Polyfluoroalkylbenzodiazepines; 1," <i>Journal of Medicinal Chemistry</i> , 16:1354-1360, (1973).
	DI	Tacke and Zilch, "Sila-substitution--a useful strategy for drug design?" <i>Endeavour</i> , 10:191-197, (1986).

Examiner Signature /Nizal Chandrakumar/	Date Considered 09/25/2010
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Disclosure Form (PTO-1449)



Sheet 5 of 5

Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	Attorney's Docket No. <b>18202-028US1/1112US</b>	Application No. <b>10/590,119</b>
	Applicant <b>ZHI et al.</b>	
	Filing Date <b>August 18, 2006</b>	Group Art Unit <b>1751</b>

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
/N.C./	DJ	Tumbull et al., "The Reaction of 4-Substituted Aryl Isocyanates with NaBH <sub>4</sub> /Trifluoroacetic Acid (TFA)," <i>Synthesis</i> , 3:391-392, (1999).
/N.C./	DK	Yin et al., "Key structural features of nonsteroidal ligands for binding and activation of the androgen receptor," <i>Molecular Pharmacology</i> , 63(1):211-223, (2003).
/N.C./	DL	Zhi and Martinborough, "Selective androgen receptor modulators (SARMs)," <i>Annual Reports in Medicinal Chemistry</i> , 36:169-180, (2001).
/N.C./	DM	Zhi et al., "Switching androgen receptor antagonists to agonists by modifying C-ring substituents on piperidino[3,2-g]quinolinone," <i>Bioorganic and Medicinal Chemistry Letters</i> , 9(7):1009-1012, (1999).
/N.C./	DN	Zhi et al., "Nonsteroidal progesterone receptor antagonists based on 6-thiophenehydroquinolines," <i>Bioorganic and Medicinal Chemistry Letters</i> , 10:415-418, (2000).

Examiner Signature <u>Nizal Chandrakumar/</u>	Date Considered <u>09/25/2010</u>
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